Exhibit D

Company Name: Ocular Therapeutix Inc
Company Ticker: OCUL US
Date: 2017-05-05
Event Description: Q1 2017 Earnings Call
Market Cap: 221.49
Current PX: 7.63
YTD Change($): -.74
YTD Change(%): -8.841
Bloomberg Estimates - EPS
Current Quarter: -0.543
Current Year: -2.202
Bloomberg Estimates - Sales
Current Quarter: 0.510
Current Year: 2.232

Q1 2017 Earnings Call

Company Participants

- George Migausky, Interim Chief Financial Officer
- Amar Sawhney, Chief Executive Officer
- Andy Hurley, Chief Commercial Officer
- Eric Ankerud, Executive Vice President

Other Participants

- Ken Cacciatore, Analyst
- Donald Ellis, Analyst
- Elemer Piros, Analyst
- Dane Leone, Analyst
- Andrew Berens, Analyst

Presentation

Operator

Good morning, ladies and gentlemen. Thank you for standing by, and welcome to the Ocular Therapeutix Conference Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session and instructions will follow at that time.

It's now my pleasure to turn the call over to George Migausky, Interim Chief Financial Officer of Ocular Therapeutix. Please go ahead, sir.

George Migausky, Interim Chief Financial Officer

Thank you, and good morning, everyone, and thanks for joining us on our first quarter 2017 financial results and business update conference call. Earlier this morning, we issued a press release providing an update on the company's product development programs and details of the company's financial results for the first quarter ended March 31, 2017. Press release can be accessed on the Investor portion of our website at investors.ocutx.com.

And joining me today on the call is Dr. Amar Sawhney our President, CEO and Chairman; as well as Andy Hurley, our Chief Commercial Officer. Amar will provide a brief summary of our recent clinical and corporate developments, and Andy will review the status of our commercial launch prep for DEXTENZA. I will then provide an overview of the financial highlights for the first quarter of 2017, before we open up the call for questions.

As a reminder, during today's call, we will be making certain forward-looking statements. Various remarks that we make during the call about the company's future expectations, plans and prospects do -- these do constitute forward-looking statements for purposes of the Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995.

Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the Risk Factors section of our most recent annual report or our actual report on Form 10-Q which was filed earlier this morning with the SEC. In addition, any forward-looking statements

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represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our views change.

And now, I'll turn the call over to Amar.

Amar Sawhney, Chief Executive Officer

Thank you, George. Good morning, everyone, and thank you for joining us. We continue to make strong progress across our programs and execute on our diversification strategy, as we seek to improve the standard of care across multiple disease stage within ophthalmology, including glaucoma, cataracts and age-related macular degeneration, the three leading causes of blindness.

We are leveraging our hydrogel technology platform to develop five drug product solutions, targeting seven discrete indications. DEXTENZA will be our first drug product and is being developed for the treatment of ocular pain following ophthalmic surgery. We hope to broaden its label to include an indication for post-surgical inflammation.

Current clinical trials are also investigating DEXTENZA in treatment of allergic conjunctivitis. Our deep product development pipeline includes OTX-TP, travoprost insert, and OTX-TIC travoprost depot to treat glaucoma and OTX-TKI and anti-VEGF depots for the treatment of retinal diseases such as age-related macular degeneration, diabetic macular edema, and retinal vein occlusion.

Our approach to product development utilizes FDA approved active agents, with proven efficacy in ophthalmology, which we enhance to form uniquely differentiated drug products via our unique delivery technology. Our drugs enhance the patient and provider experience by providing compliance, convenience, eliminating preservatives and preserving -- preventing peaks [ph] and valleys of drug concentration.

We believe this approach decreases risks and make the technology highly applicable across the broad spectrum of diseases and disorders within ophthalmology. Notably, our programs target a combined market opportunity of more than $11 billion in the United States alone. As many of you know, we're nearing a July 19th PDUFA target action date for our lead product candidate DEXTENZA for the treatment of ocular pain following ophthalmic surgery.

Following a re-inspection of our manufacturing operations by the FDA, which was actually completed just yesterday, we received the Form 483 containing inspectional observations focusing on procedures for manufacturing processes and analytical testing related to manufacture of drug product for commercial production. We plan to evaluate these observations and respond to the FDA in 15 days with corrective action plans to complete the inspection process. A timely resolution of the 483 observations is a prerequisite to keep the PDUFA date on track. We continue to work collaboratively with the FDA as they complete their review of our NDA.

DEXTENZA has been extensively studied in over 550 clinical trial participants, in a very comprehensive Phase 3 program. We believe that if approved, DEXTENZA will serve as an attractive alternative for steroid eye drops, the current standard of care for post-surgical ocular pain. Simply stated, the quantity and complexity of postoperative eye drop regimen creates compliance challenges that lead to suboptimal patient outcomes.

In an observational study, over 92% of post cataract surgery patients showed improper technique when using steroid eye drops ranging from missing the eye, instilling the incorrect amount or contaminating the bottle tip. As a result, many of these patients revisit their doctor for continued medical treatment, which impedes any healing process and is extremely frustrating for the patient, the ophthalmologists as well as their office staff. DEXTENZA delivers control to the ophthalmologists that improves patient compliance, coupled with limited toxicity concerns.

In a third-party survey, nearly 80% of ophthalmologists stated that DEXTENZA could become their new postoperative standard of care. We will have numerous presentations at the ARVO and ASCRS meetings next week, many of which will be on DEXTENZA. So there is a lot of good data getting out there and excitement in the clinical community continues to build nicely.

Our focus at ASCRS will be to share Phase 3 safety and efficacy data and patient reported outcomes results for DEXTENZA with two poster presentations. Additionally, oral presentations on preservatives and topical ophthalmic medications, adherence to glaucoma therapy and postoperative presentations on pain assessment following surgery and on a Phase 3 clinical development program for OTX-TP for the treatment of open angle glaucoma or ocular hypertension will also be presented.

At ARVO, we will be focusing on preclinical studies of OTX-TKI with four poster presentations reporting on efficacy, tolerability, pharmacokinetics of this product. We will also present an integrated analysis across three clinical trials evaluating clinical safety of DEXTENZA.

Other ARVO presentations will include four DEXTENZA posters on safety and efficacy in ocular pain and inflammation following cataract surgery. Another poster will present a Phase 2b study outcome evaluating safety and efficacy of OTX-TP and a final poster will present outcomes in cataract surgery using ReSure Sealant.

Right now the company is laser focused on ensuring that DEXTENZA, if approved, will have a robust reception in the marketplace. I will let Andy review the strategy, status, and timelines of our commercial launch planning and reimbursement ground work for DEXTENZA in a few minutes. As a reminder, if DEXTENZA is approved for postsurgical ocular pain by the July 19th, PDUFA date, we intend to submit an NDA supplement for DEXTENZA to broaden its label to include an indication for postsurgical ocular information as well.

Along with preparing for DEXTENZA's potential launch, we continue to rapidly advance our additional clinical programs in parallel. To that end, we recently initiated a non-significant risk device study with DEXTENZA for the treatment of allergic conjunctivitis. This study proposes to confirm the effect on efficacy of the placebo insert used in our previous studies compared with a rapidly reserving placebo insert. Subject to favorable results from the study, we plan to conduct an additional Phase 3 clinical trial before the revaluate DEXTENZA for the treatment of allergic conjunctivitis.

We also continue to make strong enrollment progress with our first Phase 3 clinical trial with OTX-TP for the treatment of glaucoma and ocular hypertension. The study is expected to enroll approximately 550 patients with glaucoma or ocular hypertension across 50 clinical sites in the United States. Here nearly all clinical sites up and running and are very pleased with the pace of enrollment progress we have made to date.

The primary efficacy endpoint is statistically superior reduction of intraocular pressure from baseline with OTX-TP compared to placebo at three diurnal time points of 8 AM, 10 AM, and 4 PM at intervals of 2, 6, and 12 weeks following insertion. The Phase 3 study design does not include a timolol comparator or validation arm, and does not have active or placebo eye drops administered in either arm.

The comparator arm utilizes a nondrug eluting hydrogel-based intracanalicular insert. As we have previously stated, we expect to commence our second Phase 3 clinical trial with OTX-TP for the treatment of glaucoma and ocular hypertension in the second half of 2017. As many of you know, glaucoma is a very significant market opportunity, almost 2.7 million Americans age 40 and older have been diagnosed with the disease with over 35.6 million glaucoma prescriptions in 2016.

Compliance is also a major issue in this patient population and we believe a three-month sustained release therapy like OTX-TP could be a paradigm shifting therapy.

As I mentioned, during our last update, we are also developing an intracameral product candidate OTX-TIC, which is a bio resorbable travoprost containing hydrogel depot, delivered with a fine gauge needle injection. We're developing this product candidate to address the need for a higher level of intraocular pressure reduction for some patients who have moderate to severe glaucoma, where for example 7 millimeters to 9 millimeters of IOP decrease is desirable.

These patients are often placed on multiple drugs or combination drugs and/or undergo invasive surgery to achieve this level of effect. Our initial target duration for our release with OTX-TIC is up to four months. Preclinical studies to-date have demonstrated good safety, clinically meaningful intraocular pressure lowering and favorable pharmacokinetics in the aqueous humor.

We expect to initiate a pilot human clinical trial outside the United States in the second half of 2017 to assess safety and obtain initial efficacy data. The study is expected to be a prospective, single-center, randomized double masked, sham-controlled study to evaluate the safety, initial efficacy and tolerability of OTX-TIC compared to travoprost eye drops in up to 20 patients with open angle glaucoma or ocular hypertension. If the results of this trial are promising, we've planned to advance OTX-TIC into a Phase 2 clinical development program in the United States.

Along with our partner Regeneron, we continue to make good progress on the development of a sustained release formulation of the VEGF trap, aflibercept or Eylea, as well as other protein-based biologics targeting VEGF for the treatment of serious retinal diseases such as wet AMD. As a reminder, Regeneron has the option to obtain an exclusive license to our hydrogel depot technology in combination with Regeneron's large molecule VEGF targeting compounds for ophthalmic indications. Upon excising of the option, we will receive a payment of $10 million from Regeneron and Ocular Therapeutix will be responsible for funding development through Phase 1.

Moreover, we continue to advance our tyrosine-kinase inhibitor or intravitreal depot program known as OTX-TKI. OTX-TKI is a preformed, bioresorbable hydrogel fiber depot with anti-angiogenic properties delivered by intravitreal tyrosine kinase inhibitor injection. At ARVO next week, we will be presenting for the first time results on efficacy, tolerability, and pharmacokinetics with OTX-TKI for the potential treatment of retinal diseases. We are very excited about this program, and believe that OTX-TKI will enter human clinical trials in the second half of this year.

Lastly, I would also like to acknowledge the recent appointment of George Migausky as our Interim CFO. George brings over 30 years of experience in senior financial management, most recently having served as Executive Vice President and CFO of Dyax. We are excited to have him on board, especially as we near our July 19th PDUFA date for DEXTENZA.

I would now like to turn the call over to Andy, who will summarize the status of our commercial launch preparation activities for DEXTENZA. Go ahead, Andy.

Andy Hurley, Chief Commercial Officer

Great. Thanks, Amar. As Amar alluded to, postsurgical ocular pain is an important and underserved market opportunity. Sales of single agent corticosteroids for ocular use in the US totaled approximately $800 million in 2016. This is comprised of roughly 8.5 million steroid prescriptions; about 6 million are for use following surgical procedures. Of the 6 million, about 4 million are US post cataract surgery, the most commonly performed surgical procedure in the United States Medicare eligible population.

This is our target market, and we're in the process of building out a differentiated commercial model that includes dedicated external and internal sales forces to focus on selling the clinical value of DEXTENZA. A field reimbursement team that is right sized to provide all target customers, ample support and a reimbursement hub team that will provide a suite of resources to AFCs [ph] to facilitate a seamless reimbursement process for DEXTENZA.

We believe this commercial model will be positively viewed by our customers and how we bring value to them beyond our differentiated drug products. As I've said previously, if the FDA grants marketing approval for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery, we expect to apply for a pass-through reimbursement code or C-code to be used in the hospital outpatient and ambulatory surgery center settings.

Pass-through payments provide temporary transitional reimbursement for innovative new products for a period of three years. If DEXTENZA is approved by its PDUFA date, we would plan to apply for the C-code by September 1st, as the application process is quarterly. The C-code if approved, will then become effective on January 1st, 2018.

We are proceeding with the hiring of our Ocular Therapeutix sales and reimbursement leadership, and upon DEXTENZA's approval, we plan to utilize a contract sales organization of approximately 70 sales representatives and 35 reimbursement managers to support the launch of DEXTENZA in the US. Utilizing a CSO should allow us to increase expediency to market and our CSO partner continues to do a very good job in recruit -- recruiting our desired profile for sales and reimbursement leadership.

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Our sales and reimbursement teams will be 100% dedicated to DEXTENZA. And we will be focused on the highest volume ophthalmic surgeons, AFCs, and hospital outpatient departments that represent the top 80% of the business potential for DEXTENZA.

With a product that goes through a C-code reimbursement process, it is important to get surgeons and their office staff comfortable with the reimbursement coding and process to get medical claims paid for the drugs they utilize. They could be completely comfortable with the product clinically, but if they don't understand the reimbursement cascade that needs to happen if these claims to be processed and paid, frustration installing of reimbursement can potentially occur.

Therefore, as part of our early experience program that we plan to conduct between the potential approval of DEXTENZA and the C-code being in place, we will be proactive in educating surgeons on the attributes of DEXTENZA and supporting surgery days for physicians to get comfortable with the administration and clinical value of DEXTENZA.

We will also be proactive in talking with the staff within the ambulatory surgery centers and the hospital outpatient departments to inform them of the services offered to providers and patients by our internal reimbursement hub. The hub is meant to provide offices with the resource to help manage the reimbursement process through the payer channel, and essentially serve as a concierge service for reimbursement.

In parallel, we continue to conduct payer research to understand payer dynamics across the commercial and Medicare advantage books of business, and how best to facilitate access to DEXTENZA across each specific managed care plan.

During the pass-through transitional period of three years, we would have the ability to have DEXTENZA carved out from the facility fee and fully reimbursed through Medicare Part B. We also plan to file for an extending J-code, which would continue full reimbursement beyond the three year period.

From a medical affairs perspective, our medical team has hired experienced MSLs, who will target key opinion leaders, who we believe could educate the population of ophthalmic surgeons that perform the vast majority of cataract surgeries, about 6,500 surgeons in the United States.

Our goal here is to ensure that the surgeons are educated with respect to DEXTENZA, as well as our hydrogel platform both prior to and during our launch, and having the C-code being in place. The familiarity with the product candidate is strong and the excitement in the clinical community continues to build. As Amar mentioned, we will have numerous presentations on DEXTENZA at the ASCRS and ARVO meetings next week.

With that, I will now turn the call back over to George, who will review our first quarter 2017 financial results.

George Migausky, Interim Chief Financial Officer

Thanks, Andy. So let me begin by summarizing our capitalization as of March 31, 2017. At that date, we had $80.4 million in cash, cash equivalents, and marketable securities. This includes the net proceeds from our offering that was completed back in January. We also have an active At-the-Market program or an ATM, under which shares of our common stock may be sold from time-to-time.

And in March, we amended the terms of our existing credit facility to increase the total commitment to $38 million. This $38 million facility included $18 million that was funded at closing, which was used primarily to pay-off the outstanding balances as of the closing date, and also includes options on two additional tranches of $10 million each. The availability of these tranches are based on the achievement of certain regulatory and commercial milestones. For our shares outstanding, we had approximately 28.9 million shares issued in outstanding at March 31, 2017.

Now with respect to operations during Q1, our operating cash burn was $14 million in the first quarter of 2017. And consistent with what we've previously discussed and as we've seen in Q1, we expect that our operating cash burn will increase significantly in 2017 as compared to 2016. This is primarily due to the pre-commercialization activities

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relating to DEXTENZA, our launch preparation and subject to FDA approval, the after launch of DEXTENZA.

In addition, we are advancing our clinical development programs including our Phase 3 glaucoma trials. It's important for me to note that while we are investing in pre-commercialization activities in advance of the potential approval of DEXTENZA, the hiring of our field sales force and reimbursement team will be contingent on FDA approval.

We expect that our existing cash, cash equivalents, and marketing -- marketable securities will be sufficient to fund our operating expenses, our debt service and capital expenditures through the second quarter of 2018. This is of course subject to a number of assumptions about our clinical development programs, commercialization of DEXTENZA and other aspects of our business. We will need to raise additional capital to fund the full commercial launch of DEXTENZA subject to approval by the FDA.

Now for our reported financial results. For the first quarter ended March 31, 2017, we reported a net loss of $16 million, which is a loss of $0.58 per share. This compares to a net loss of $10.8 million and $0.44 per share for the first quarter of 2016. The net loss for the first quarter of 2017 included $2 million in non-cash charges for stock-based compensation and depreciation compared to $1.6 million for similar non-cash charges in 2016.

Research and development expenses totaled $6.7 million in the first quarter of 2017 compared to $7.1 million in the first quarter of 2016, as we continue to advance the clinical and preclinical development of our hydrogel platform technology and the portfolio of drug product candidates.

Selling and marketing expenses for the quarter ended March 31, 2017 were $6 million compared to $1.4 million last year. The 2017 (sic) increase represents the costs of pre-commercial activities in preparation for the planned commercial launch of DEXTENZA.

Our revenues for the first quarter of 2017 totaled approximately $500,000 from the sales of ReSure Sealant. And as noted in the past, we don't expect product revenues from the sales of ReSure to be material in 2017.

So this concludes my comments on our first quarter 2017 financial results. And for the upcoming Q&A, Amar, Andy, and I are also joined by Dr. Jon Talamo. our Chief Medical Officer; and Eric Ankerud, our Executive Vice President of Regulatory, Quality and Compliance.

So, now let me turn the call back over to the operator, so we can go ahead and take your questions.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from the line of Ken Cacciatore from Cowen & Company. Go ahead please. Your line is open.

Ken Cacciatore, Analyst

Hey, guys. Just looking to expand a little bit on the 483s and a little bit more specific what they're looking for and then maybe a little bit more specificity on what you think you need to do to resolve that, and I think you said 15 days, but there is much more nuance you can give us around that issue?

And then, on OTX-TP, you indicated that enrollment is moving along well with the first Phase 3. Can you just help us frame and I know it's always tough to narrow down, when we might see that top line data just -- any window you could give us that you think that, that might be available would be fantastic? Thank you.

Amar Sawhney, Chief Executive Officer

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Yeah. Thanks, Ken. So let me first respond to the second part of your question, and then I will let Eric Ankerud respond to the first part of your question.

With regards to OTX-TP, the enrollment is going well, we're close to about a 100 patients enrolled in the study, which as you know is a 550 patients study. So, we expect to complete enrollment through this year. And then by the middle of next year around -- end of second quarter of next year, we expect to be able to share some top line data on that. So that's sort of the timeline on OTX-TP.

The second of the efficacy trials would -- its currently planned to be initiated in the second half of this year. So that's -- it's a similarly sized trial, similar number of sites et cetera.

Ken Cacciatore, Analyst

And Amar before you move on to the next one, will we be using the same plug or we had made some modifications, so the second Phase 3 may have an even more optimized product?

Amar Sawhney, Chief Executive Officer

No, we're going to be using the same plug.

Ken Cacciatore, Analyst

Okay. Thank you.

Amar Sawhney, Chief Executive Officer

So, now moving on to the 483 and few of the nuances on that, I will turn it over to Eric.

Eric Ankerud, Executive Vice President

Good morning, Ken. Thanks for the question. FDA completed the re-inspection of our facility as part of the NDA review late yesterday afternoon. As Amar mentioned, 483 was issued. We were pleased during the re-inspection that the FDA investigator was able to confirm our corrective action plan from prior observations, and indicated that there was no further follow-up necessary to close out those issues.

This was a new investigator not the same investigator from prior inspections, and their primary focus in the 483 relates to a particular matter issue as part of our manufacturing process. The issue relates primarily to completion of an investigation that we have underway in regard to the particular matter solidifying specifications for in process, 100% visual inspection of our inserts, as well as enhancing our operator training.

We feel quite comfortable that we have the situation under control and we are preparing responses to the 483 as of this morning in anticipation of responding within 15 calendar days to the agency. In addition to the particular matter issue, FDA raised a couple of observations in regard to analytical method, testing to be completed, as well as some other issue related to quality oversight of batch records.

So in summary, we believe that each of the observations raised by FDA during this continuous improvement review of our fully developed manufacturing process are handled well and will be resolved in our response to FDA. We're also pleased that the collaborative nature of our NDA review has continued between the various offices of FDA, and we're marching toward that PDUFA date and expect that we can resolve the 483 issues in a timely manner.

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Ken Cacciatore, Analyst

Okay. Thank you.

Operator

Your next question comes from the line of Donald Ellis from JMP Securities. Go ahead please. Your line is open.

Donald Ellis, Analyst

Thank you, and good morning, guys. Regarding the 483, will there be a requirement for re-inspection? And then my second question regarding -- is regarding the C-code pass-through. What gives you comfort that a pass-through code will be granted for this product? Thanks.

Amar Sawhney, Chief Executive Officer

So, I will let Eric answer the question on the 483. And then, Andy, maybe you can weigh in after that on the commercial stuff.

Eric Ankerud, Executive Vice President

As a result of the completion of the re-inspection yesterday afternoon, there is no indication of a re-inspection needed going forward.

Donald Ellis, Analyst

Terrific. Okay.

Andy Hurley, Chief Commercial Officer

Yeah. And Donald, this is Andy. On the C-code, couple of things that give us comfort. If there is a precedent in a pathway that other companies have followed, we've been able to get a lot of counsel and consultants really helping us, really understand the process by which we need to undertake in order to get a C-code. And basically it's the guidelines of what needs to happen is, you need to have a -- an FDA approved product that has to be novel and innovative, which is one clearly is. And then you have to establish a pricing that is quote on quote not insignificant in relation to the corresponding CPT or Current Procedural Terminology, the procedural code which is the $1,700 for cataract surgery in the hospital outpatient setting.

So really when you look at all the stipulations that need to go with a C-code, we feel all of them, and we will set our pricing accordingly, so we will meet the threshold that needs to occur in order to be considered that non-insignificant price versus the cataract surgical procedure. We've had two other companies where they've gone through this process and we've been able to follow their pathway and how they've been able to do it. And ultimately we're just spending a good amount of time making sure that we have all of the i's dotted and the t's crossed so that our application process is as good as it possibly can be. So we're very confident.

Donald Ellis, Analyst

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Okay. So that the first three years is very clear. Obviously, doctors are going to want to use the product. What happens after three years?

Andy Hurley, Chief Commercial Officer

Yeah, so what we're going to be doing is, during the C-code term, which is a full three years, our goal would be to drive business across not only the ambulatory surgery centers, but we're going to be in the hospital outpatient departments as well. Once we are now getting some traction in the marketplace, we're going to file for an extending J-code. The J-code application process is once a year. So if all goes well, which we're expecting it will for PDUFA and go July 19th, then we would be able to apply for an extending J-code which would offer the opportunity for DEXTENZA to be reimbursed in an office space landscape.

And so that's what we -- our plan would be is that, in January of 2018 we would be filing for that extending J-code, which would not make it a miscellaneous code, it will be a permanent J-code, and then that would be in effect January 19. So during the time which we have our C-code, the C-code would actually transfer over to the J-code and we will have a J-code that would extend the life of the products. And that is our plan.

Donald Ellis, Analyst

Great. Thank you very much.

Andy Hurley, Chief Commercial Officer

You're welcome.

Operator

Your next question comes from the line of Andrew Berens from Morgan Stanley. Please go ahead, please. Your line is open.

Andrew Berens, Analyst

Hi. Thanks for taking the question. I was just wondering, you mentioned that there is some sort of testing or validation necessary that was discovered yesterday. What is that, and how long do you expect this (technical difficulty)?

Amar Sawhney, Chief Executive Officer

So it's not a validation. So just to be clear, there is no validation. It is -- basically they're looking for a test method for DEXTENZA through -- an accelerated absorption to be able to demonstrate that the product is stable through the details [ph]. But just to kind of have the material liquefy in a shorter period of time and show that the dexamethasone is -- in two weeks or so to show that the dexamethasone is not altered. So it's a standard test that we do, we just need to sort of provide them, it's underway, we will provide them better information.

Eric Ankerud, Executive Vice President

It's about a two-week test. So it's a very short test that we could complete and shouldn't delay anything.

Andrew Berens, Analyst

Okay. Is there anything in their observations that you think could delay the action date specifically?

Amar Sawhney, Chief Executive Officer

Nothing that we can currently see. I think these -- as you know, probably 90% plus inspections have 483. The question is, what are the nature of the issues in the 483? We think these are resolvable issues, and we have responses. Some are already prepared and some being prepared to address them in a timely fashion.

Operator

Your next question comes from the line of Elemer Piros from Cantor. Go ahead please. Your line is open.

Elemer Piros, Analyst

Yes, good morning, gentlemen. My questions were asked and answered. So, thank you very much.

Andy Hurley, Chief Commercial Officer

Thank you, Elemer.

Operator

Your next question comes from the line of Dane Leone from BTIG. Go ahead please. Your line is open.

Dane Leone, Analyst

Hi. Thanks for taking the questions. So, maybe we could just be more specific. Did the FDA explicitly state that there is not going to be a re-inspection?

Amar Sawhney, Chief Executive Officer

In an inspection they never say that, they're not going to say that that there is not going to be another inspection or not. Basically that determination is not actually made by the inspector. So, it would be --

Dane Leone, Analyst

When would you know whether you need an additional inspection?

Amar Sawhney, Chief Executive Officer

You won't know that until you actually -- if you get a CRL or something of that sort, then you do that. But there is no evidence right now or nothing pointing towards that direction. So, can it theoretically happen? Yes. Is it our read that is likely going to happen? Probably not.

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Dane Leone, Analyst

And then, I guess, what specifically gives you confidence that is not going to happen? Because it seems like there is a number of things that were brought up on this 483.

Amar Sawhney, Chief Executive Officer

Yeah, because most of the issues that are brought up on the 483 are not long-term type of issues. These are quality system and method methodology type of things that are to be addressed by modifications of training procedures, documentation and in one case the test method that is a relatively short-term type of a test method. But Eric can comment a little bit on that.

Eric Ankerud, Executive Vice President

Yes, in addition to that, we have commercial product in our controlled inventory and that was something FDA was looking for as part of this re-inspection as a sign that we're ready to go for a commercial launch.

Dane Leone, Analyst

I guess, yeah, I guess specifically to what you said as adequate inspector training. I guess can you respond to that in a written form, or it just seems like that that may be something that they would want to see confirmed visually or no?

Eric Ankerud, Executive Vice President

No, I think this is a 100% visual inspection of the insert in process during manufacturing, and we have training tools available to the operators. The FDA investigators offered some other recommended tools to be used and we believe that those can enhance the operator's ability to detect defects and so we are moving forward in that direction. But I don't think it's anything that FDA to come back and look at. It's well understood by both parties.

Amar Sawhney, Chief Executive Officer

So it's like having the description of what you need to be looking at in a training manual versus being right above on a poster sitting above the operators chair. So that type of stuff.

Dane Leone, Analyst

So they -- basically said, listen, this isn't in the training manual and it should be. Is that what you're saying?

Amar Sawhney, Chief Executive Officer

No, it is in the --

Eric Ankerud, Executive Vice President

No, it's in the training manual. They were offering other suggestions of how the training could be enhanced. The operators are trained for this visual inspection. FDA was indicating that in order to enhance that training there are

further steps that could be taken.

Dane Leone, Analyst

Okay. So they were suggestions or requirements?

Eric Ankerud, Executive Vice President

Well, the 483 is something that we have to respond to, but we had a good discussion with FDA during the re-inspection. So we understand where they're coming from and what needs to be done to address their concern.

Dane Leone, Analyst

Okay. And so just from a macro point of view, the manufacturing questions have been in overhang for two years now. I guess, how -- is there something you can tell us or say to us in terms of how things have evolved at the company overall and oversight of manufacturing that would bring, I guess, a higher degree of comfort that these issues are ultimately going to stop happening, I guess?

Eric Ankerud, Executive Vice President

I think there is two important issues to recognize. The first is that from the prior preapproval inspection, FDA issued a 483. We resolve those issues, close those issues with the district office and during this re-inspection the new investigator is responsible for confirming that we have implemented what was said in our responses. And the investigator went through each of our responses and confirm that we had properly and appropriately implemented those actions.

So I think that's a strong sign that the manufacturing process has moved forward significantly, and is in a fully developed mode. I think the other point to recognize is that we are educating ourselves and FDA by the fact that this is not a typical drug product. This is not an ophthalmic drop nor is it a tablet or a pill. This is a hydrogel delivery system carrying an API. And so that is part of the manufacturing process, which we are very familiar with, we're very familiar with building hydrogel products.

And so it's an education process for FDA that they recognize. And so we continue the dialog and continue that process and that is something that went through this re-inspection and we had a -- as I said, a new investigator and the new investigator was experienced in the pharmaceutical industry and we had good dialog and good discussion and that's why we felt confident that we can address these 483 issues in a timely manner.

Amar Sawhney, Chief Executive Officer

I just want to make sure, Dane, you've kind of appreciated the fact that 90% being I actually asked the inspector how many of these inspections result in 483? And they said, well -- or don't result in the 483, and they said well I could remember may be two in the last three years. So over 90% of them will have observation.

The question is what is the nature of these observations. Also remembering that this is a new investigator, different one that came last time. So when you have a different one coming, they confirm what the prior one did, and then they probably have some additional helpful suggestions. Question is, can these suggestions be resolved in a reasonable period of time and that's what we're hoping, is the case.

Company Name: Ocular Therapeutix Inc
Company Ticker: OCUL US
Date: 2017-05-05
Event Description: Q1 2017 Earnings Call
Market Cap: 221.49
Current PX: 7.63
YTD Change($): -.74
YTD Change(%): -8.841
Bloomberg Estimates - EPS
Current Quarter: -0.543
Current Year: -2.202
Bloomberg Estimates - Sales
Current Quarter: 0.510
Current Year: 2.232

Dane Leone, Analyst

Okay. Maybe we can switch gears to the TKI initiative.

Amar Sawhney, Chief Executive Officer

Yes.

Dane Leone, Analyst

I'm curious to understand how from a regulatory perspective you will have to proceed. Obviously, you're using APIs in your hydrogel formula in other areas that are well advanced, but for TKI specifically that's kind of a different ballgame. And I'm just curious how you get -- give comfort and get comfort in terms of progressing into clinical trials, running an integrated formulated TKI and not having to do maybe like a naked TKI like injected into the eye or something like that. I'm not sure if I am asking that correctly, but --

Amar Sawhney, Chief Executive Officer

Are you concerned about the protocol design or are you concerned about regulatory submission? Are you concerned about masking and sham or are you concerned more about --

Dane Leone, Analyst

It's more about sustained like initially going in with a sustained delivery product of the TKI, which have more hard to predict adverse events. I'm just curious how that factors in from a regulatory perspective? Are they okay going directly in with a novel TKI or at least a novel TKI not from a target basis, but something that hasn't been tested before in a sustained release format for something, for whatever reason if there is an unforeseen event -- adverse event that becomes kind of problematic. I was just curious of what your thoughts are on that?

Amar Sawhney, Chief Executive Officer

A couple of things. The depot form actually help to ensure that the drug is localized in one location and should there be an issue, it can be removed by a vitrectomy. So it's not like if you were to inject in a powder, which by the way there have been many clinical trials with TKIs where people have injected in powders and solution forms and other like things, which are much harder to remove.

So -- and those trials have actually proceeded in the past. So it's not like people have not conducted clinical trials with TKIs in the back of the eye. Arguably putting it in a depot and having it localized, so it can be removed should there be any issues would be relatively easy. The third part of that is that that this TKI that we're selecting from a systemic standpoint at least is an approved oncology drug. So it has got a lot of history of safety.

Fourth point is that we have conducted extensive amount of preclinical testing in various species and just like entering any clinical trial have all the necessary safety information that would be needed to conduct such a study. I mean everything starts at some point.

Dane Leone, Analyst

Okay.

Amar Sawhney, Chief Executive Officer

(inaudible) very, very good from what we've seen pre-clinically.

Dane Leone, Analyst

Okay. And just a last point on that is -- has something, since you called out the Regeneron partnership in the press release and on the call here, did something specifically progress forward in that development pathway over the last three months or since your last update?

Amar Sawhney, Chief Executive Officer

So, it's hard for us to comment given that this is something that we have to collaboratively speak about. So we cannot make unilateral statements. All I would say is that the relationship is progressing nicely, and they're continued to be very enthused about the progress that is being made and we have provided them with, product candidates that they're in the process of testing and feel that -- that's going in the right direction.

Operator

I'm showing no further questions at this time. I'll now turn the call back over to Dr. Amar Sawhney for closing remarks.

Amar Sawhney, Chief Executive Officer

I want to thank everybody for taking the time to join us on the call today. We look forward to updating you in the coming months as we approach our PDUFA date for DEXTENZA. On behalf of the entire Ocular team, thank you for all your support. You may now disconnect.